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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,448	09/01/2005	Rakhi H. Rohra	RG/G-32840A	1580
72554	7590	08/21/2009	EXAMINER	
SANDOZ INC 506 CARNEFIE CENTER PRINCETON, NJ 08540			SILVERMAN, ERIC E	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			08/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,448	Applicant(s) ROHRA ET AL.	
	Examiner ERIC E. SILVERMAN	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-10 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/22335 in view of US 4,716,153 to Morishita.

The WO '335 reference teaches compositions comprising clarithromycin (a macrolide antibiotic), sodium-calcium alginate, and citric acid. Claim 17.

What is lacking is a teaching of the inorganic salt of instant claims.

Morishita teaches that macrolide antibiotics can be stabilized by adding a stabilizer that has a pH of 3-10 in aqueous media. Abstract. The stabilizer may be, for example, an inorganic salt antacid such as calcium hydrogen phosphate, disodium hydrogen phosphate, dipotassium hydrogen phosphate or magnesium hydrogen phosphate. Col. 9. Addition of the stabilizer prevents the ring from decomposing quickly to demycarosyl or isodemycarosyl forms. *Id.* The stability is achieved by adding the stabilizer to acidic solutions. The amount of the stabilizer is not crucial, so long as sufficient stabilizer is added to achieve the a pH increase to 3 or more; Morishita notes that decomposition is reduced by 70% at pH 2, by 80% at pH 2.5, and by more than 90% at pH 3. *Id.* Morishita suggests that 50 mg of stabilizer will be sufficient to

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stabilize 100 mg of drug, although the reference prefers to use additional stabilizer as this does not have any negative effect on the system. Col. 9-10. Morishita also teaches that a dissolution rate accelerator, such as sodium hydrogen phosphate, may be added. Claim 11. The compositions may be formulated into tablets. Examples.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to add a salt of instant claims, such as calcium hydrogen phosphate, disodium hydrogen phosphate, dipotassium hydrogen phosphate or magnesium hydrogen phosphate, to the composition of WO '355. The suggestion to do so comes from Morishita, who teaches that such salts stabilize otherwise rapidly degrading macrolides. In addition, or in the alternative, the artisan would add a different salt of instant claims, sodium hydrogen phosphate, following Morishita's suggestion to use that salt as a dissolution accelerator in macrolide tablets. With regard to the amount of stabilizer, the only requirement is that the amount be sufficient to raise the solution pH to 3 or higher, and Morishita suggests that a ratio of stabilizer to macrolide of about 1:2 would be sufficient.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Primary Examiner, Art Unit 1618